

## Validation Report (Ref.VAL-005)

### Process Description

(Describe the process which is due to Operational Qualification)

### Objective

The objective of the Operations Qualification is to perform a series of tests to determine that the operation of the equipment/process conforms to the specifications.

The tests conducted are outlined in Part 4. of this report. Each individual test function listed has the acceptance criteria specified.

### Instrumentation/Calibration

- All critical equipment instrumentation was calibrated as a part of the Installation Qualification. Calibration reports are included as attachments to the Installation Qualification Report.
- All critical test instrumentation was calibrated prior to testing and again when testing is complete. Calibration reports are included as attachments to the Operational Qualification Test Protocol.
- All tests were carried out to a level of accuracy indicated by the acceptance criteria.
- All calibrations were performed as per an approved SOP.

### Test Functions performed in the Operational Qualification phase and overall results obtained

	Test Functions	Acceptance Criteria	Results
1.			
2.			
3.			

### Additional Validation Requirements

Refer to Validation Plan for the inclusion of the following sections:

<b>EHS Audit</b> Safety, Health and Environmental	<b>Report No :</b>
All critical EHS observations are addressed and closed	

<b>Internal Quality Audit</b> ( Note: For new process lines only )	<b>Report No:</b>
All GMP related observations are addressed and closed	Yes / No – Sign & Date

<b>Training and Procedures</b>	<b>All training requirements stated in the Validation Plan has been</b>
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